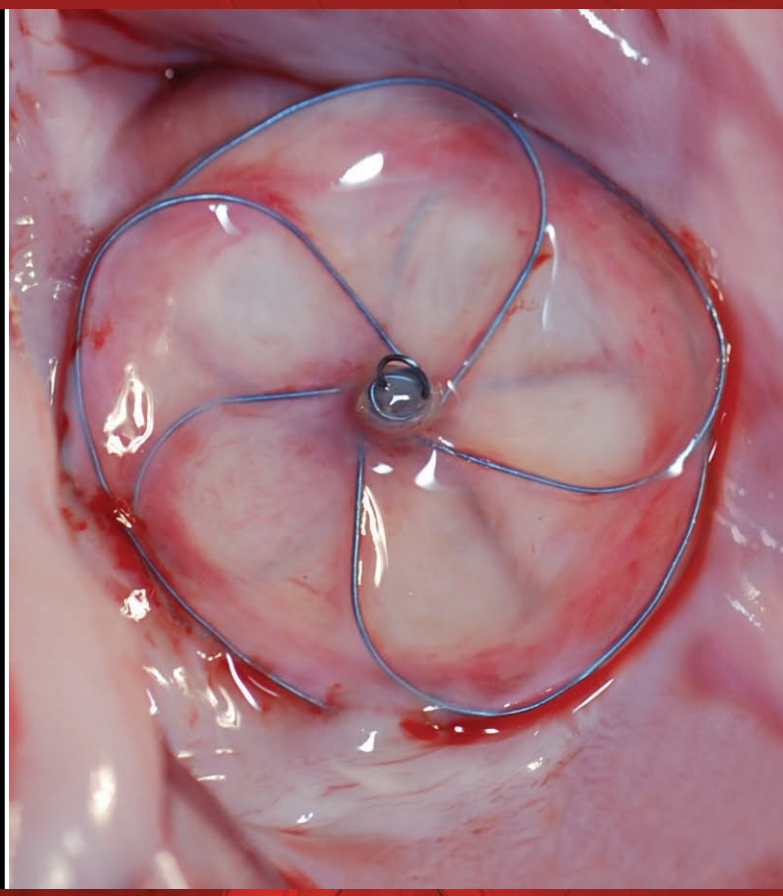
Case Study



Closure of a Multi-fenestrated Defect with GORE® CARDIOFORM Septal Occluder

GORE CARDIOFORM SEPTAL OCCLUDER

PERFORMANCE by design

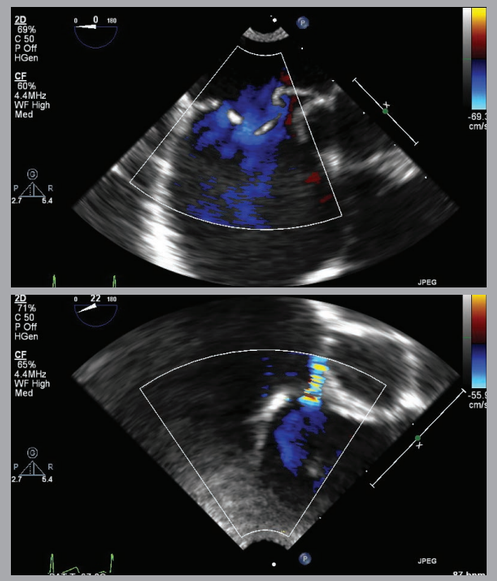


Figure 1. *Transesophageal echocardiography (TEE) demonstrating a multi-fenestrated, aneurysmal septum with at least four separate defects in the septum primum (top) and at the retroaortic rim (bottom).*

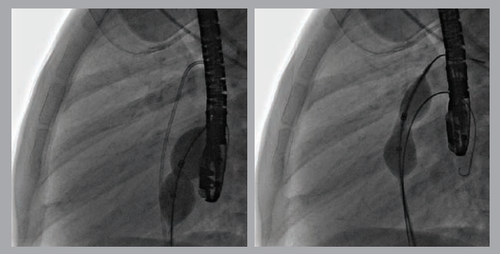


Figure 2. *Lateral fluoroscopy showing balloon sizing of the inferior (left) and anterior (right) defects. The inferior defect measured 8 mm and the anterior defect measured 5 mm.*

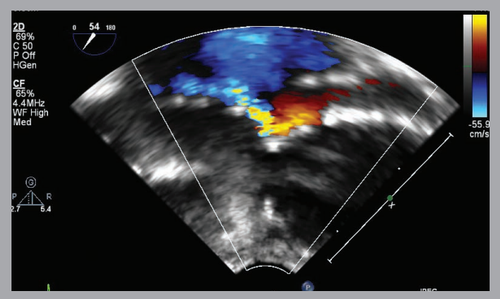


Figure 3. *TEE demonstrating that the residual shunting across the septum was smallest during balloon sizing of the inferior defect.*

CASE STUDY

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This case presents a ten year old (34 kg) asymptomatic child with a moderate fenestrated secundum atrial septal defect with atrial septal aneurysm referred for transcatheter atrial septal defect closure.

Procedure

The patient was brought to the cardiac catheterization laboratory and placed under general anesthesia. Antibiotics were given. A baseline transesophageal echocardiogram demonstrated right heart enlargement. Interrogation of the atrial septum revealed a multi-fenestrated secundum atrial septal defect with a prominent atrial septal aneurysm. There were at least four defects present (*Figure 1*).

Vascular access was achieved in the right groin with a 7 Fr sheath in the right femoral vein, a 3 Fr sheath in the left femoral vein, and a 2 Fr monitoring line in the left femoral artery. Double venous access was planned in the event that simultaneous placement of overlapping devices would be required. Heparin was administered. Right and left heart hemodynamics and a main pulmonary artery angiogram were obtained. There was a significant step-up in saturation from 69% in the superior vena cava to 85% in the branch pulmonary arteries. The Qp:Qs ratio was 2.1:1, and indexed pulmonary vascular resistance was 0.6 wood units.

A multipurpose catheter was advanced across an inferior fenestration, and used to position a SAFE-T-J® Rosen Curved Wire Guide 0.035" in the left lower pulmonary vein. A 24 mm AMPLATZER Sizing Balloon II was then advanced across the atrial septum. The 'stop flow' stretched diameter of this fenestration was 8 mm (*Figure 2 left*). Maintaining the balloon in that position, a 5 Fr AL2 catheter was used to cross an anterosuperior fenestration and enter the left upper pulmonary vein. The sizing balloon was then placed through this anterior defect, and the stretched diameter was 5 mm (*Figure 2 right*). Both balloon inflations were evaluated carefully on the echocardiogram to determine the degree of residual shunting, and proximity of that shunting to the sizing balloon. The smallest residual shunting was seen with the sizing balloon across the larger, inferior fenestration (*Figure 3*).

The optimal device would have to cover all fenestrations and have enough radial strength to eliminate all shunting. Considering the total atrial septal length of 38 mm on the baseline transthoracic study, a 30 mm GORE® CARDIOFORM Septal Occluder was chosen. The delivery system was flushed, and the device was loaded under sterile saline in the recommended fashion. The delivery catheter was placed over the monorail SAFE-T-J® Rosen Curved Wire Guide and advanced into the mid left atrium. The wire was removed. The left atrial disc was deployed and the delivery catheter was brought toward the septum. The right disc was then deployed. The device appearance was quite flat on fluoroscopy (*Figure 4*). On the transesophageal echocardiogram the device was well positioned with no significant residual shunt. The device was locked and there was some reorientation due to releasing the tension on the septum from the delivery system. The device was well positioned on the echocardiogram and fluoroscopy, with a trivial left-to-right shunt in the retroaortic region by color Doppler (*Figure 5*). The patient was observed overnight and discharged the

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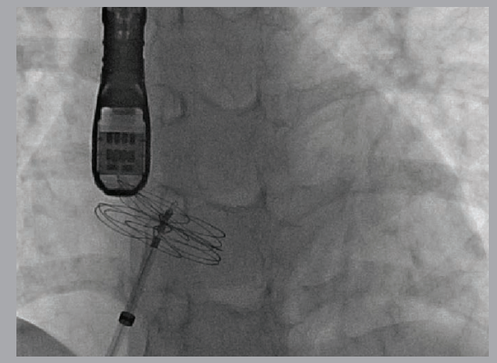

Figure 4. *Fluoroscopy showing the fully formed Occluder before the device is locked.*

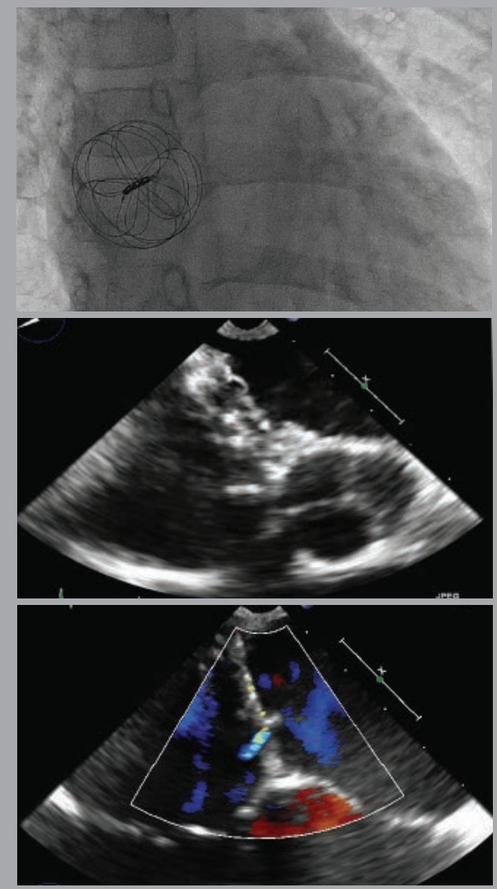

Figure 5. *The device was well positioned on fluoroscopy and echocardiography, with a small superior residual shunt.*

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following day. The trivial anterosuperior residual shunt was present the following day, but had resolved by one-month follow-up. The device remained flat with no residual shunt and no interference with other intracardiac structures at one-year follow-up (*Figure 6*).

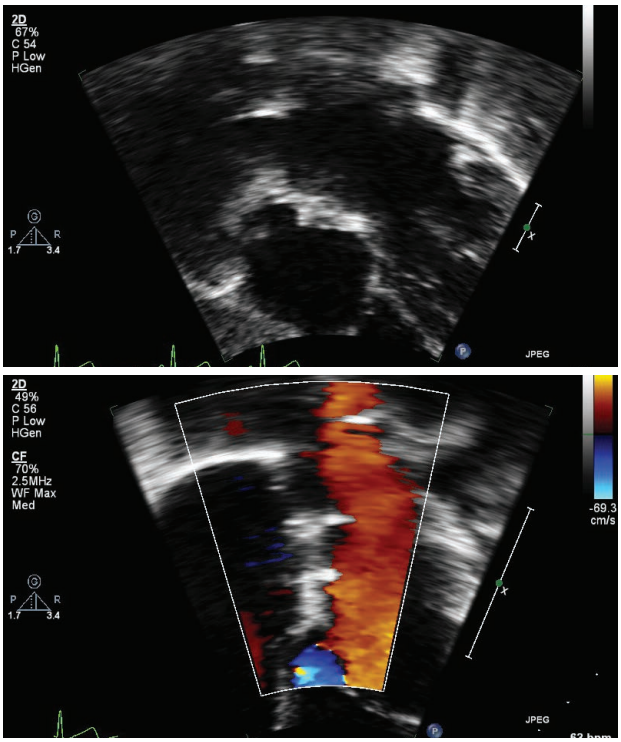

Figure 6. *Follow-up subcostal Transthoracic Echocardiogram (TTE) one year after implant (top) demonstrating flat device appearance in the septum. Color flow Doppler in a zoomed four chamber TTE shows no residual shunting (bottom).*

Discussion

Multi-fenestrated atrial defects can be challenging to address in children, particularly because of the length of the atrial septum compared to that of an adult. These defects may require closure with more than one device, and regardless of device choice, they may have significant residual shunting. Careful interrogation of the size and location of all fenestrations by echocardiogram is essential in this setting. The use of double venous access and balloon sizing in this particular case was helpful to determine the relationship among the various fenestrations, and the optimal fenestration through which to place the device.

In this case, the GORE® CARDIOFORM Septal Occluder was an excellent choice. The 30 mm device was positioned across one of the more central fenestrations. The device design does not require the operator to be across the largest fenestration. Upon lock release, this device had enough septal apposition to eliminate the atrial septal aneurysm, and virtually all shunting, immediately. The trivial residual shunt seen in the procedure and the following day had resolved by one month. At one year follow-up, the right heart has normalized in size, and there continues to be no residual shunting.

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